No. 27

In the Supreme Court of the United States

OCTOBER TERM, 1958

ARTHUR S. FLEMMING, SECRETARY OF HEALTH, EDUCATION AND WELFARE, PETITIONER

v.

FLORIDA CITRUS EXCHANGE, FRANK B. SCHELL, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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I

THE FOOD ADDITIVES AMENDMENT APPROVED ON SEPTEMBER 6, 1958 DOES NOT AFFECT THIS CASE

A. After the petitioner's brief was filed, the Food Additives Amendment of 1958, Public Law 85–929, was approved. The earliest effective date of its enforcement provisions (Section 3) will be March 5, 1959 (Section 6).

The new amendment provides in pertinent part as follows:

> SEC. 402. A food shall be deemed to be adulterated—
> * * * (2) (*A*) if it bears or contains any added poisonous or added deleterious substance

(except a pesticide chemical in or on a raw agricultural commodity *and except a food additive*) which is unsafe within the meaning of section 406, or (*B*) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408 (a), or (*C*) *if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409.* * * * [New material emphasized.]

"Food additive" is defined in Section 201 (s) as:

> * * * any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food * * *), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use * * *.

"Food additives" are declared to be unsafe unless their use is permitted by an exemption or a regulation prescribing the conditions under which such an additive may be safely used (Sec. 409 (a)).

Any person is authorized to file a petition to establish the safety of a food additive for its intended use, submitting among other things data to show what the

intended effect is and that full investigations have been made with respect to the safety of the additive (Sec. 409 (b)). The Secretary is directed to act on the petition by establishing the necessary regulation or exemption to guarantee safe use or by refusing to do so (Sec. 409 (c)). No such regulation may issue if the data fails to establish that the proposed use of the food additive will be safe, or if the data shows the additive would promote deception of the consumer or would otherwise result in adulteration or misbranding of food. And if a tolerance limitation is required to assure safe use, the tolerance is to be fixed no higher than is needed to accomplish the intended physical or technical effect (Sec. 409 (c) (3) and (4)).

The law requires the Secretary to consider the probable consumption levels for the additive, the cumulative effect of it, as well as of any chemically or pharmacologically related substances, in the diet, and to apply appropriate safety factors in evaluating the animal experimentation data (Sec. 409 (c) (5)).

The prime purpose of this amendment was to prohibit the use in food of additives before their safety for their intended use had been adequately investigated and firmly established. And if the safety could be thus established, the additive was no longer forbidden solely because it was a poisonous or deleterious substance. Safe amounts may be tolerated at the lowest levels required to accomplish the intended effect.

B. We have difficulty in understanding why respondents believe that this new law aids their cause.

In the first place, it has no applicability to coal-tar colors. Neither respondent contends otherwise, but they seek in some way to use the new law to influence the meaning of "harmless" in Section 406 (b). In the second place, the new law makes it clear that it is the duty of the user of an additive to prove that the additive will be safe. Respondents cannot show this as to Red 32.

1. We believe the new provisions wholly inapplicable to coal-tar colors.[1]

Congress did not amend Section 406 (b), which deals specifically with coal-tar colors, on which the Secretary's order in this case was based. Indeed, the very same Committee which developed the new law, the House Committee on Interstate and Foreign Commerce, had before it H. R. 8945, a bill to authorize the Secretary to establish safe tolerances for coal-tar and other color additives. The Department of Health, Education, and Welfare reported on the bill by letter dated June 27, 1958. No hearings were held, and the bill died with the adjournment of Congress.[2]

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[1] The press release by the Department of Health, Education, and Welfare on the new law contains the following sentence: "Antioxidants, mold inhibitors, rancidity prevention agents and other preservatives, emulsifiers, stabilizers, extenders, colors, flavors, bleaching agents and thickening agents are examples of the type of additives which are covered." It does not say that coal-tar colors are covered.

[2] The Department of Justice also reported on this bill in June 1958, and told the Congress that its enactment would render the present litigation moot. But the Food Additive Amendment, which does not apply to coal-tar colors, does not make the litigation moot. So long as Section 406 (b) remains in the law, this case retains the importance that brought it here.

This separate consideration of the status of coal-tar colors is consistent with the Congressional policy followed in Section 406 (a) and (b), as discussed in our main brief. And until Congress revises the policy of allowing the certification only of coal-tar colors that are wholly harmless, the provisions of Section 406 (b) must be followed.

2. But even if the Secretary has power to permit use of a coal-tar color under tolerances, and even if the new legislation can be said to suggest a policy to be followed in that situation, the new legislation is not yet effective and the facts do not exist on which a safe tolerance for Red 32 can be established even for oranges.

In an effort to minimize the poisonous character of Red 32, respondents assert that all that is shown on this record is that Red 32, like all other substances, is toxic when consumed in massive and excessive amounts bearing no relation to the amount likely to be consumed from color-added oranges.

The amounts tested, 100 ppm. and 400 ppm. in dogs and 1000 ppm. and 2500 ppm. in rats, are in no real sense massive doses. They were chosen by qualified pharmacologists as proper amounts to be added to the test diets to answer the question whether the dye could be regarded as harmless for unrestricted use in food—whether in the diet it could be regarded as innocuous. These tests are clearly relevant to the question the Secretary was called upon to decide.

In contrast, respondents base their entire claim that Red 32 is harmless when used on oranges on certain claimed admissions of the Commissioner of Food and

Drugs and of Secretary Folsom. These are drawn from a letter to Senator Smathers, a letter to Congressman Haley, a press release, and testimony and a report on the bill, H. R. 7732, 84th Cong. (Fla. Cit. Br. 21–22; Schell Br. 39, 60–61, 84–85), which was enacted into the temporary legislation discussed on pages 10–12 of our main brief. A fair reading of these materials, all outside the record, establishes these salient facts:—Red 32 is a poisonous substance when fed to laboratory test animals; exactly how poisonous it is not known because the lowest level fed to the test dogs—100 parts per million—killed one of the dogs; until the precise toxicity of the color is established, together with its probable intake under all likely patterns of consumption, we cannot say that there is a likelihood of injury to man from consumption of color-added oranges; nor can we say with assurance that the practice is a wholly safe one.[3] The fact that no injuries to man have been attributed to Red 32 on oranges is, as the Secretary found (Finding 9, R. 163–164), of little significance "because few people know what colors they are eating" and the delayed toxic effects to vital organs and processes would not have been attributed to the color even if caused by it.

Under the new legislation, this kind of inconclusive evidence of safety would not result in permission to use an additive. It was to deal with precisely this

[3] While both respondents repeatedly assert that the Department of Health, Education, and Welfare admits there is no possibility whatever of harm from color-added oranges, the most that can be said is that the likelihood of harm from this single food is not believed to be great, but is actually unknown (cf. Fla. Cit. Br. 53).

sort of situation in the case of food additives in general that the Food Additives Amendment of 1958 was enacted. There was an important loophole in the Federal Food, Drug, and Cosmetic Act which permitted the use of chemicals in food though their toxicity was either unknown or uncertain. The Government could not prevent the use of a chemical in food until it was prepared to prove that the substance was in fact a poisonous or deleterious one. This meant that the questionable chemical could be used without evidence that it was safe; the Government had the burden of conducting the necessary scientific investigation to determine whether the chemical was a poisonous or deleterious one, and while the scientific investigation of its toxicity was underway it could be used. If the chemical finally turned out after testing to be poisonous, it could be removed from the diet, but only after the harm had been done. H. Rept. 2284, pp. 1–2, 4–5; S. Rept. 2422, pp. 1–3, 6–7, 85th Cong., 2d Sess.

The new law will relax to some extent the stringent prohibition against all added poisonous and deleterious substances, discussed on pages 36–41 of our brief.[4] But this same new law will exclude from the food supply all chemical substances that are not definitely known to be safe for their intended use. All questions of doubt are to be resolved against the

[4] Section 406 (a) will now apply to added poisonous and deleterious substances that accidentally contaminate foods during production and in the manufacturing processes. Intentional food additives used to accomplish some desired physical or technical effect in the food will be controlled by the new law. Section 409 (b) (1) and (c) (3), Public Law 85–929, Section 4.

chemicals and in favor of the consumer. Proof positive is needed before the chemical can be used.

So even if the new statute applied to Red 32 on Texas and Florida oranges—which it does not—the practice could not be tolerated until there can be an affirmative showing that it is entirely a safe one. Congress, by the temporary legislation, gave the growers a moratorium of three years to develop a color that is not toxic or to explore further the toxicity of Red 32 to obtain the facts on which a safe tolerance could perhaps be based (Pet. Br. 10–11). This further evidence clearly would be required before Red 32 could be tolerated as a food additive.

II

RESPONDENTS' ATTACKS ON THE FINDINGS OF FACT ARE WITHOUT MERIT

1. Both lower courts (the Second Circuit and the Fifth Circuit below) have sustained the Secretary's evidence. Nonetheless, respondent Schell attacks the critical finding that no safe level of dosage for Red 32 has been established even for the test animals, by asserting that the test was improperly conducted in bad faith, and that the results are refuted by other experiments both before and after[8] the test in question (Schell Br. 15, 32–39). The Citrus Exchange complains that the findings ignored certain essential

[8] The subsequent test relied upon is made an appendix to Schell's brief. It was done by Canadian investigators. It involved rats, not dogs. It lasted only 20 and 44 weeks, instead of the life span of two years, and could not refute the dog studies. We discussed Canada's action on these three colors in footnote 22, p. 49, of our main brief.

findings of fact, which he made on uncontroverted

testimony (Br. 11), and that the Secretary failed to meet the burden of proof (Br. 15). A portion of the testimony is quoted (Br. 17–19) out of context to cast doubt on the findings. And the significance of the findings is challenged by the Gerwe analysis (Br. 23), which wholly fails to take account of the injury to the test dog at 100 ppm. Finally, there is a reproduction of testimony from the 1939 hearings (Br. 30–32) which implies that no coal-tar color is harmless and suitable for use in all kinds and classes of foods, drugs, and cosmetics. A full reading of the old testimony shows that the single exception the witness was discussing was coal-tar colors to be applied to the area of the eye.

It is, of course, true that the tests on which the Secretary's findings were based were not designed to show whether color-added *oranges* are safe. They were designed to explore whether the colors were harmless for *unrestricted* use in food, drugs, and cosmetics. The evidence shows that they are not (R. 217). The sole scientific witness said:

> The dyes in question are at present being certified for use in foods, drugs, and cosmetics, and the data which we presented in these exhibits have shown that they are not harmless for use in all of those products.

For the reasons set forth in our main brief, we believe that the Secretary has under the statute no power to determine whether Red 32 would be safe on oranges alone; authority to make that determination must come from Congress. But, in any event, as developed *supra*, pp. 5–8, it is plain that whether

Red 32 might be safe for use on oranges alone cannot now be determined on the known facts. With an amended law and a sound factual basis on likely consumption levels and the true toxic potential of the color, it might be possible to fix a safe tolerance for Red 32 on one or more foods. But no such law or such facts now exist.[6]

2. Respondents also argue that all coal-tar colors are toxic; that Congress knew this in 1938; and that therefore it is unreasonable to prevent the use of coal-tar colors which are not wholly safe. This is not so. The legislative history and administrative background of the coal-tar color certification provisions plainly show that both Congress and the administrative officials thought that "most", but not all, coal-tar colors were toxic. The conception of the law was to forbid use of the toxic colors, while permitting the unrestricted use of the innocuous ones.

That policy has been followed since 1907. The Secretary, in reporting on H. R. 8945, *supra*, p. 4, recognized that new scientific studies are proving this to be a stringent test and are eliminating colors from the list which have long been on it. This is why the Secretary asked fresh Congressional guidance in this field. Several colors remain on the list, however, under the harm-

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[6] Finding 10 is cited by respondents as saying that colors are used in so many foods that the establishment of proper tolerances would be impossible (Schell Br. 51). What the finding says, however, is that there is now no proper factual or legal basis for establishing a safe tolerance for the three colors in a variety of foods.

less classification. If the use of harmful colors is to be permitted, Congress must grant the authorization.[1]

Respectfully submitted.

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NOVEMBER 1958.

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[1] Respondents argue that it is unreasonable to bar all use of a toxic coal-tar color when toxic ingredients such as arsenic may be used in their manufacture (Schell Br. 63). The tolerances for arsenic, etc., are, however, fixed at levels which give assurance that the color, when certified, is itself harmless. The test of harmlessness in the statute applies to the finished coal-tar color, not to the ingredients comprising it. The legislative history of the coal-tar color provisions shows that Congress intended the Secretary to so limit the necessary impurities in coal-tar colors that the colors themselves would be harmless.

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